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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER	
ULM, J	
ART UNIT	**PAPER NUMBER**
1812	7

DATE MAILED: 01/30/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1 to 11 is/are pending in the application.

Of the above, claim(s) 4 to 6, 10, 11 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1 to 3, 7 to 9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☑ Claims 1 to 11 are subject to restriction or election requirement.

Application Papers

☑ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ ~~Notice of Reference Cited, PTO-892~~

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

★ U.S. GPO: 1996-409-290/40029

1) Claims 1 to 11 are pending in the instant application.

2) Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 to 3 and 7 to 9, drawn to a nucleic acid encoding a CALR protein, a vector and host cell containing that nucleic acid and a process of producing the protein encoded thereby, classified in Class 435, subclass 69.1.

II. Claims 4 and 5, drawn to a diagnostic test, classified in Class 435, subclass 6.

III. Claim 6, drawn to a antisense nucleic acid, classified in Class 536, subclass 24.3.

IV. Claim 10, drawn to a CALR polypeptide, classified in Class 530, subclass 350.

V. Claim 11, drawn to a compound of unspecified constitution, classified in Class undeterminable, subclass undeterminable.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acid that is invention I, the nucleic acid that is invention III, the polypeptide that is invention IV and the compound that is invention V are different and distinct chemical compositions. Distinctness is shown by the fact that each of these compositions can be made and used without the other and because they lack a common utility which is based upon a common

special technical feature. For example, the nucleic acid that is invention I can be used to make the protein encoded thereby whereas the nucleic acid of invention III can not.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acid that is invention I can be used to make the protein encoded thereby, which is a materially different process that the diagnostic test that is invention II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification restriction for examination purposes as indicated is proper.

During a telephone conversation with Debra J. Glaister on 02 August of 1996 a provisional election was made with traverse to prosecute the invention of group I, claims 1 to 3 and 7 to 9. Affirmation of this election must be made by applicant in responding to this Office action. Claims 4 to 6, 10 and 11 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

3) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the nucleotide sequences presented in line 33 on page 3 of the instant specification and both of the amino acid sequences presented in Figures 2A to 2D therein. Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37

C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claims 1, 2 and 7 to 9 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to an isolated and purified polynucleotide encoding the amino acid sequence shown in SEQ ID NO:2, an isolated and purified polynucleotide comprising the nucleotide sequence shown in SEQ ID NO:1, a vector comprising one of those polynucleotides, a host cell comprising that vector, and a method of producing a protein comprising the amino acid sequence shown in SEQ ID NO:2, said method comprising the steps of culturing a host cell containing a heterologous nucleic acid encoding said

receptor under conditions suitable for expression of said protein by said cell, and recovering said protein.

Because the instant specification does not identify that property or combination of properties which is unique to, and therefore definitive of, a CALR protein it is not possible to determine what is encompassed and what is excluded by this term in the absence of some reference to SEQ ID NO:2 of the instant application. Further, the definition of "CALR" which is given on page 4 of the instant specification indicates that this term encompasses "C5a-like receptor homologs" having "essentially the sequence shown in SEQ ID No 2". The instant specification, however, does not identify those amino acid residues in SEQ ID NO:2 which are essential for the functionality and structural integrity of a CALR protein and those residues which are expendable or substitutable. In fact, as stated above, the instant specification does not even demonstrate a functionality for the disclosed protein. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or

> electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Because the instant specification does not identify those residues of SEQ ID NO:2 which are critical to CALR, identify a structurally analogous protein from which this information could be obtained or provide working examples of CALR proteins whose amino acid sequences deviate from SEQ ID NO:2, an artisan can not employ known scientific law to produce a CALR protein whose amino acid sequence deviates from SEQ ID NO:2 at even a single residue and predict the performance characteristics of that protein. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The instant application is not enabling for the production of a nucleic acid encoding a "CALR homolog". The instant application describes a recombinant nucleic acid encoding a putative receptor protein which is identified therein a "CALR". A homolog of CALR would be a protein which serves an analogous function to CALR but which is in a different organism. The instant application is totally devoid of a written description of a homolog of CALR or a nucleic acid encoding such a homolog. Further, since the instant application does not disclose the natural function of CALR then one would not be able to recognize

a homolog thereof since the term "homolog" is functionally defined.

5) Claims 1 to 3 and 7 to 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1) Claim 1 is incorrect because there is no antecedent basis for "the" CALR homolog. Neither the art of record or the instant specification identify a single protein as "the" homolog of the CALR protein which is described in the instant specification. Claims 2, 3 and 7 to 9 are incorrect in so far as they depend from claim 1 for this element.

5.2) Claim 2 is vague and indefinite because the limitation "overexpression" is relative and no point of reference is provided.

6) Claim 9 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim. 35 U.S.C. § 112, fourth paragraph, requires a dependant claim to further limit the subject matter **claimed** in the claim from which it depends.

7) Applicant is advised that claims directed to an isolated and purified polynucleotide encoding the amino acid sequence shown in SEQ ID NO:2, an isolated and purified

polynucleotide comprising the nucleotide sequence shown in SEQ ID NO:1, a vector comprising one of those polynucleotides, a host cell comprising that vector, and a method of producing a protein comprising the amino acid sequence shown in SEQ ID NO:2, said method comprising the steps of culturing a host cell containing a heterologous nucleic acid encoding said receptor under conditions suitable for expression of said protein by said cell, and recovering said protein would be free of the prior art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm at telephone number (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM. The fax phone number for this group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800